

APR 24 2003

K030388

Page 1 of 3

**510(k) Summary  
Bionx Implants Inc.  
Impact™ Suture Anchor**

**Submitter's Name, Address, Telephone Number, and Contact Person**

Bionx Implants, Inc.  
1777 Sentry Parkway West  
Gwynedd Hall, Suite 400  
Blue Bell, PA 19422

Contacts: Gerard S. Carlozzi  
President and Chief Executive Officer  
Phone: (215) 643-5000  
Facsimile: (215) 653-0984

Bionx Implants Ltd.  
Tuija Annala  
Director, Quality and Regulatory Affairs  
P.O.Box 3  
FIN-33721 Tampere  
Finland  
Phone: 358-3-316 5679  
Facsimile: 358-3-316 5629

**Date prepared:** January 28, 2003

**Name of the device:**

- |    |                            |   |
|----|----------------------------|---|
| A. | Trade or Proprietary Name: | Impact™ Suture Anchor                               |
| B. | Common Name:               | Bioabsorbable suture anchor                         |
| C. | Classification Name:       | Biodegradable soft tissue fixation fastener (87MAI) |
| D. | Device Product Code:       | MAI   |
| E. | Regulatory Classification: | Class II  |

**Predicate Device:**

The Impact™ Suture Anchor is intended for use in the reattachment of soft tissue to bone by arthroscopy or direct visualization. This indication is substantial equivalent with Bionx Implants Inc. Duet™ Suture Anchor (K020056), SmartAnchor

(K972783), Bankart Tack (K973849), Contour Labral Nail (K992567, K003970), BioCuff™ (K001378) and BioCuff™ C (K013057), Arthrex Inc. Bio-Absorbable Corkscrew (K990361) Bio-Absorbable Corkscrew Suture Anchor (K990987), Bio-Absorbable CorkScrew Suture Anchor (K003227) and TissueTak (K990340), Innovasive Devices, Inc. BioROC EZ (K973381), RC Multi-Suture Anchor (K992458) and Sutureless Anchor (K984490), Instrument Makar, Inc, Biologically Quiet Biosphere (K963396) and Biologically Quiet Mini-Screw Suture Anchor (K960555), Linvatec Corporation Bio-Anchor (K964805, K963369, K983186) and BioRC Anchor (K990110), Mitek Surgical Products Panalok (K950272), Panalok RC (K970896) and Absorbable Toggle Anchor (K964013), Acufex Inc. Suretac 6.0, 8.0 (K911837) and DePuy Inc. De Puy Dupont Phantom Suture Anchor (K964921).

### **Intended Use:**

The Bionx Impact™ Suture Anchor is a bioabsorbable screw-in suture anchor that is preloaded on a disposable inserter device with two non-absorbable, braided, polyester #2 sutures. The Impact™ Suture Anchor is manufactured from Self-Reinforced (96/4D) PLA Copolymer that retains 90% strength through 20 weeks and completely resorbs over a period of several years in vivo. The unique Self-Reinforced Copolymer provides high initial mechanical strength required for insertion and through the healing phase (20 weeks) with complete absorption occurring over several years. The unique absorption profile of the Copolymer allows the anchor to gradually lose strength as the collagen fibres of the repair form and gain strength. The Copolymer is inert, non-collagenous and non-pyrogenic through the absorption process. The Impact™ Suture Anchor is indicated for use in arthroscopic or open surgical procedures to reattach soft tissue to the bone.

The Impact™ Suture Anchor is contraindicated in the following conditions:

1. Surgical procedures other than those listed.
2. Conditions that may compromise Anchor fixation (osteopenic, comminuted bone, pathologic conditions in the soft tissues to be attached, etc.)
3. Conditions that may retard healing (poor blood supply, past or potential infection, etc).
4. Active infection.
5. Conditions that may limit the patients ability or willingness to restrict activities or follow directions during the healing period.
6. Foreign body sensitivity to materials.
7. Patients with suspected or known allergy to the implant or suture materials.

### **Device Description:**

Impact™ Suture Anchor is a smooth, cylindrical/conical shape, bioabsorbable, push-in suture anchor, provided as preloaded with two non-absorbable, braided, polyester #2 sutures, one of them is green and another one is white. Colour of green suture is D&C Green No 6, white suture represents original colour of polyester suture. Diameter of the anchor is 3.5mm and length 10.5mm. It is assembled with sutures

with needles into single use, sterile, disposable driver and packaged into blister with a drill bit. The Impact™ Suture Anchor is made of poly-L/D-lactide copolymer. The poly-L/D-lactide material equals the raw material used in previously cleared Bionx Implants Inc. Duet™ Suture Anchor (K020056), SmartNail™ (K993074), Meniscus Arrow™ (K993453), SmartScrew ACL™ (K993073), SmartScrew (K012001), The Wedge™ (K000616), Contour Labral Nail (K003970), BioCuff (K001378) and BioCuff C (K013057).

**Substantial Equivalence:**

All of these devices have the same intended use and principles of operation and very similar technological characteristics. Furthermore, the minor technological differences between the Bionx Implants Inc. Impact™ Suture Anchor and the predicate devices do not raise any new issues of safety or effectiveness.



APR 24 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Tuija Annala  
Director, Quality and Regulatory Affairs  
Bionx Implants Ltd.  
Hermiankatu 6-8 L  
FIN-33720 Tampere  
Finland

Re: K030388

Trade/Device Name: Impact™ Suture Anchor  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: January 28, 2003  
Received: February 5, 2003

Dear Ms. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

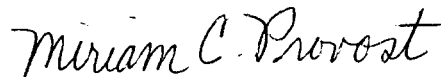
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE

510(K) Number (if known): K030388

Device Name: **Impact™ Suture Anchor**

### Indications for Use:

The Bionx Impact™ Suture Anchor is intended for use to reattach soft tissue to bone in orthopaedic surgical procedures. The device may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules, to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

The Bionx Impact™ Suture Anchor is contraindicated in 1) Surgical procedures other than those listed, 2) Conditions that may compromise Anchor fixation (osteopenic, osteoporotic, comminuted bone, pathologic conditions in the soft tissues to be attached, etc.), 3) Conditions that may retard healing (poor blood supply, past or potential infection, etc), 4) Active infection, 5) Conditions that may limit the patients ability or willingness to restrict activities or follow directions during the healing period, 6) Foreign body sensitivity to materials, 7) Patients with suspected or known allergy with implant or suture materials.

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes  
(Per 21 CFR 801.109)

OR Over-The-Counter Use No

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K030388